



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 17 2010

Re: IXIARO
Docket No. FDA-2009-E-0416

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 6,309,650 filed by Chiel Jedang Corp & Walter Reed Army Institute of Research, under 35 U.S.C. § 156. The human biological product claimed by the patent is IXIARO (Japanese Encephalitis Virus, Vaccine Inactivated, Adsorbed), which was assigned biologics license application (BLA) No. B125280/0.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1).

The BLA was approved on March 30, 2009, which makes the submission of the patent term extension application on May 28, 2009, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Jane A. Axelrad".

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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cc: William T. Christiansen, Ph.D.
SEED Intellectual Property Law Group, PLLC.
701 Fifth Avenue, Suite 5400
Seattle, WA 98104